

Listing of Claims:

Claims 1-4 (canceled)

Claim 5 (newly added)

A test kit comprising radiolabeled 25-hydroxyvitamin D₃, unlabeled 25-hydroxyvitamin D₃ and instructions for the measurement of vitamin D binding proteins in urine as a marker for salt sensitivity in individuals.

Claim 6 (newly added)

A method of determining specific 25-hydroxyvitamin D binding activity in a urine sample comprising the steps of:

- (1) preparing multiple identical samples of urine collected from an individual;
- (2) adding a known amount of radiolabeled 25-hydroxyvitamin D₃ to all samples in step (1);
- (3) adding a known amount of excess unlabeled 25-hydroxyvitamin D to half of the samples prepared in step (2) to compete with radiolabeled 25-hydroxyvitamin D₃ for binding proteins in the urine;
- (4) incubating all samples prepared in steps (2) and (3) to allow radiolabeled 25-hydroxyvitamin D₃ binding to proteins in the urine;
- (5) incubating samples prepared in step (4) with buffered dextran-coated charcoal, then centrifuging to precipitate the unbound radiolabeled 25-hydroxyvitamin D₃;
- (6) measuring the radioactivity in each sample;
- (7) subtracting the average radioactivity in the samples containing excess unlabeled 25-hydroxyvitamin D₃, which had been added in step (3), from the average radioactivity of the samples to which no unlabeled 25-hydroxyvitamin D₃ had been added to determine specific vitamin D binding activity in the urine with the amount of binding in samples prepared in step (3) acting as a background for the amount of binding in the samples to which 25-hydroxyvitamin D₃ has not been added.

Claim 7 (newly added)

The method of claim 3 wherein the sample tested is human urine.

Claim 8 (newly added)

The method of claim 3 wherein high 25-hydroxyvitamin D binding activity in the urine is deemed indicative of salt sensitivity or predisposition to salt-associated hypertension.

Claim 9 (newly added)

The kit of claim 5 lacking antibodies to 25 hydroxyvitamin D.

Claim 10 (newly added)

A method of calculating specific 25-hydroxyvitamin D binding activity in urine samples of an individual by subtracting binding in samples in the presence of both labeled and excess unlabeled 25-hydroxyvitamin D from binding in samples containing only labeled 25-hydroxyvitamin D₃ but to which no unlabeled 25-hydroxyvitamin D has been added to determine salt sensitivity.

Claim 11 (newly added)

The kit of claim 1 containing, additionally, dextran coated charcoal.

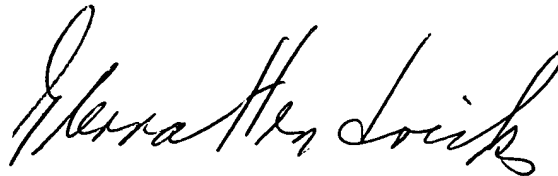
Response to Rejections and Objections of record

Claims 1-4 have been cancelled and new claims formulated to overcome the rejections relating to 35 USC 112, second paragraph. Hence, it is believed that rejection is now moot.

Claims 1 and 4 (now claims 5 and 10) have been rejected under 35 U.S.C. 103103(c) or 35 U.S.C. 103(e), (f) or (g) prior art under 35 U.S.C. 103(a). The rejection is respectfully traversed. Norman teaches a method of making a known compound, while De Luca teaches several radiolabeled vitamin D compounds. There is no suggestion that these or any related compounds be used for testing or be combined with unlabeled 1,25 hydroxyvitamin D to test for any disease or condition. Hence, there would be no motivation to combine, into one test kit, the components required in the claims in this patent application. The Examiner has used impermissible hindsight using words in the instant application to seek named compounds and has found nothing that suggests the invention as claimed.

The claims are deemed in condition for allowance. Allowance of the claims as presented is respectfully requested. If further discussion may prove useful in prosecution of this application, the Examiner is respectfully invited to call the undersigned at 703 425 8405.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Glenna Hendricks".

Glenna Hendricks, Reg. no. 32,535